NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICALS COMPANY LIMITED, TAKEDA PHARMACEUTICALS USA, INC., and TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LIMITED, Defendants.	Civ. Action No. 18-11792 (FLW) **OPINION**

WOLFSON, Chief Judge:

This matter arises from a patent infringement suit plaintiffs Takeda Pharmaceuticals Company Limited, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc. ("Takeda" or "Plaintiffs") filed against defendants Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Limited ("Zydus" or "Defendants"). After a period of discovery, Takeda voluntarily dismissed its infringement claims with prejudice. Zydus now moves for attorneys' fees pursuant to 35 U.S.C. § 285, which authorizes courts to award fees to a "prevailing party" in "exceptional cases." Because this case is not "exceptional," Zydus's motion is **DENIED**.

I. BACKGROUND AND PROCEDURAL HISTORY

Takeda manufactures the Prevacid® SoluTab ™ ("Prevacid"), an orally disintegrating tablet ("ODT") used to treat gastroesophageal reflux disease, or "acid reflux." Prevacid contains the active

ingredient lansoprazole, a proton pump inhibitor that suppresses stomach acid. The tablet dissolves in the patient's mouth, leaving behind thousands of granules that are small enough to avoid a feeling of roughness when swallowed. Takeda has filed several patent infringement suits in connection with Prevacid, which the Court summarizes herein, as they are relevant to the pending motion for attorneys' fees.

In 2010, Zydus filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration ("FDA") seeking to introduce a generic version of Prevacid. Takeda filed an infringement suit[1] in this district alleging that Zydus's generic version violated three Takeda patents, including U.S. Patent No. 6,328,994 (the "'994 Patent"), which was issued on December 11, 2001. *See* ECF No. 76-5, '994 Patent.[2] As relevant here, Claim 1 of the '994 Patent recites:

> An orally disintegrable tablet which comprises (i) fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent, said composition having 10 weight % or more of an acid-labile physiologically active substrate that is lansoprazole and (ii) an additive wherein said tablet having a hardness strength of about 1 to about 20 kg, is orally disintegrable.

See id. col. 37 ll. 43–53. The district court held a claim construction hearing pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) ("*Markman* Hearing"), after which it construed the claim term "fine granules having an average particle diameter of 400 μm or less." *Zydus I*, 2011 WL 4736306, at *2–3. Accepting Takeda's proposed construction, the district court construed the term to mean "fine granules up to and including the enteric coating layer having an *average* particle

[1] Submitting an ANDA is "by statutory definition[] an infringing act." *See In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 149 (3d Cir. 2017).

[2] The suit also alleged that the generic version infringed U.S. Patent Nos. 7,431,942 (the "'942 Patent"), issued on October 7, 2008, and 5,464,632 (the "'632 Patent"), issued on January 25, 2011. *See Takeda Pharm. Co., Ltd. v. Zydus Pharm. USA, Inc.*, Civ. No. 10-1723, 2011 WL 4736306, at *1 (D.N.J. Oct. 5, 2011) [*Zydus I*].

diameter of 400 μm (±10%) or less." *Id.* at *3–4 (emphasis added). Following a bench trial, the district court concluded that Zydus's generic version infringed the '994 Patent because the particle sizes in the generic version fell within the range specified in Claim 1. *See Takeda Pharm. Co., Ltd. v. Zydus Pharm. USA, Inc.*, Civ. No. 10-1723, ECF No. 345, slip op. at 19–21 (D.N.J. May 7, 2013).

The Federal Circuit reversed on appeal, holding that "the proper construction of the disputed claim term is 'fine granules having an average particle diameter of *precisely* 400 μm or less.'" *Takeda Pharm. Co. v. Zydus Pharms. USA Inc.*, 743 F.3d 1359, 1365 (Fed. Cir. 2014) [*Zydus II*"] (emphasis added). As support for its construction of the claim term, *Zydus II* consulted the patent's specification and prosecution history, which further supported the conclusion that the "fine granules" referenced in the claim term are those with a diameter of precisely 400 μm or less, without a ±10% margin of error. *See id.* at 1364–65. In light of the Federal Circuit's decision, the district court entered judgment against Takeda on its infringement claim in connection with the '994 Patent. *Takeda Pharm. Co, Ltd. v. Zydus Pharm. USA Inc.*, Civ. No. 10-1723, 2014 WL 12629965, at *2 (D.N.J. Oct. 16, 2014) [*Zydus III*].

Following the district court's judgment, Zydus submitted a reformulated version of its generic Prevacid in response to input from the FDA, and Takeda brought a new suit asserting the '994 Patent against Zydus's reformulated product. *See Takeda Pharm. Co. Ltd. v. Zydus Pharm. USA, Inc.*, Civ. No. 18-1994, 2021 WL 3144897, at *5–7 (D.N.J. July 26, 2021) [*Zydus Antitrust Opinion*], *appeal filed*, No. 21-2608 (3d Cir. Aug. 30, 2021). Takeda ultimately dismissed its suit voluntarily, but as part of the same litigation, Zydus filed a counterclaim arguing that Takeda sued merely to maintain its Prevacid monopoly, in violation of the Sherman Antitrust Act, 15 U.S.C. §§ 1 *et seq.*, and the New Jersey Antitrust Act, N.J.S.A. 56:9-1 *et seq*. *Id.* at *1, 9. Takeda invoked the *Noerr-Pennington* doctrine, *see id.* at *9, which extends First Amendment protection and immunity from antitrust liability to "[t]hose who petition [the] government for redress," *Pro. Real Est. Invs.,*

Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56 (1993) ("*PRE*"), including through litigation. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510, 515 (1972). In response, *Zydus* raised a narrow exception to *Noerr-Pennington* for a lawsuit that constitutes "a mere sham." *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961). To qualify, the lawsuit must be both "objectively baseless" and must "conceal an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." *PRE*, 508 U.S. at 60–61 (quotations and citations omitted). Zydus maintained that Takeda's suit was objectively baseless because *Zydus II*'s claim construction purportedly precluded infringement. *See Zydus Antitrust Opinion*, 2021 WL 3144897, at *13–14. However, this Court held that Takeda's suit against the reformulated product was not a sham because, among other reasons, testing revealed that some particles in the reformulated product fell within the size range specified in the '994 Patent, and Zydus made substantial changes to the reformulated product following *Zydus II* before gaining FDA approval. *Id.* at *16.

After dismissing its claims, Takeda initiated the instant infringement action, alleging that the reformulated product violated U.S. Patent No. 9,901,546 (the "'546 Patent"). *See* ECF No. 1, Complaint.[3] As relevant here, Claim 1 of the '546 Patent states: "An orally disintegrable tablet, which comprises: (i) fine granules comprising a composition coated with an enteric coating layer . . . ." *See* ECF No. 76-3, '546 Patent col. 37 ll. 37–40. Unlike Claim 1 of the '994 Patent, Claim 1 of the '546 Patent does not recite any specific particle size applicable to "fine granules." Zydus

[3] The '546 Patent is a continuation of the application that led to the '994 Patent. *See* ECF No. 82-1, Declaration of Dr. James E. Polli ("Polli Decl.") ¶¶ 33, 43. As a "continuation" of a "common parent application," the '546 Patent "therefore necessarily" has a specification that is "almost identical" to that of the '994 Patent. *See Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1337 (Fed. Cir. 2006).

nevertheless moved to dismiss based on collateral estoppel, arguing that *Zydus II*'s construction of the term "fine granules" in the '994 Patent precluded any conclusion that Zydus's generic version infringed Claim 1 of the '546 Patent. *See* ECF No. 32 at 8–10. This Court denied the motion because, unlike Claim 1 of the '546 Patent, Claim 1 of the '994 Patent refers specifically to "fine granules having an average particle diameter of 400 μm or less," and *Zydus II* construed only the '994 Patent. *See* ECF No. 50 at 4–5. Thus, the Court concluded that *Zydus II* did not preclude Takeda's infringement suit asserting the '546 Patent. *See id.* at 5.

The parties thereafter filed *Markman* briefs seeking to construe, *inter alia*, the term "fine granules" as used in Claim 1 of the '546 Patent. *See* ECF Nos. 75, 76. Zydus proposed the following construction:

> granules having an average particle diameter of precisely 400 μm or less which do not produce a feeling of roughness in the mouth and have a maximum particle size of practically 425 μm or less wherein practically allows for about 5 weight % or less of particles whose particle diameter is out of the above described range. 'Fine granules' do not constitute 'conventional granules' that have an average particle diameter of 400 μm or more and cause a feeling of roughness in the mouth.

See ECF No. 76 at 6. Takeda argued that no construction of the term was necessary, but that if the Court chose to construe the term, it should be construed to mean "the granules of the claimed invention, *i.e.*, granules comprising a composition coated with an enteric coating layer." *See* ECF No. 75 at 8.

As support for its proposed construction, Zydus argued that *Zydus II* required a construction that limited the term "fine granules" to those with "an average particle diameter of precisely 400 μm or less." *See* ECF No. 76 at 21–24. Zydus emphasized that the Federal Circuit's construction turned not only on the claim term itself, but also on the term "fine granules" used in the specification of the '994 Patent, which is identical to the specification of the '546 Patent. *See* ECF No. 80 at 13–20. As Zydus notes, *see* ECF No. 80 at 11, "in interpreting an asserted claim, the court should look

first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification, and if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "The specification 'is always highly relevant to the claim construction analysis,'" and "'usually, it is dispositive,'" as "'it is the single best guide to the meaning of a disputed term.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (*en banc*) (quoting *Vitronics*, 90 F.3d at 1582). Here, the specification for both patents states: "The 'fine granules' have an average particle diameter of about 400 μm or less, preferably 350 μm or less. . . ." *See id.* at 21. Because the specification for both patents refers to "fine granules" with a specific particle size, Zydus maintained that the term "fine granules" used in certain claims of the '546 Patent must similarly contain a particle-size limitation consistent with *Zydus II*'s construction. *See id.* at 19.

By contrast, Takeda argued that Zydus improperly attempted to import language from the specification into Claim 1 of the '546 Patent. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). And as Takeda emphasized, *see* ECF No. 82 at 6, while courts must "read claims in view of the specification," courts may "not read limitations from the embodiments in the specification into the claims." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014), *cert denied*, *Stryker Corp. v. Hill-Rom Servs., Inc.*, 135 S. Ct. 719 (2014). Because Claim 1 of the '546 Patent does not recite a particle size, Takeda maintained that the court may not import a particle-size limitation from the specification into the claim. *See* ECF No. 82 at 6. Takeda also argued that the '546 Patent's specification referred to "fine granules" numerous times in different contexts and in connection with multiple benefits beyond particle size, *see id.* at 6–8, and, according to Takeda, the specification's reference to "fine granules having an average particle diameter of 400 μm or less" describes "a specific embodiment of fine granules."

See id. at 11–13. Finally, Takeda argued that the prosecution history of the '546 Patent supported its position, as "Takeda explicitly amended the claims of the '546 patent during prosecution to remove the particle size limitations recited in [Claim 1] of the earlier '994 [Patent], '942 [Patent], and [U.S. Patent No. 7,875,292 ("'292 Patent")]." *Id.* at 13–15, 17–20.

Before the *Markman* hearing that was scheduled for September 2020, Takeda moved pursuant to Rule 41(a)(2) to voluntarily dismiss its infringement claims as well as Defendants' counterclaims seeking declaratory judgments for non-infringement and invalidity. *See* ECF No. 89-1 at 4. Takeda dismissed the claims due to "the expiration of the '546 Patent," among other reasons. *Id.* at 4–5. Zydus did not oppose dismissal of the infringement claims, but it did oppose dismissal of the counterclaims. *See* ECF No. 92. Zydus also sought a determination that it is the prevailing party and a commitment from the Court to retain jurisdiction over claims for attorneys' fees Zydus planned to file pursuant to 35 U.S.C. § 285. *See id.* at 25. The Court granted Takeda's motion to dismiss its infringement claims but denied the motion to dismiss Zydus's counterclaims. *See* ECF No. 95. In addition, the Court deferred a decision as to whether Zydus is entitled to attorneys' fees. *Id.* at 3.[4]

Zydus then filed the present motion for attorneys' fees, contending that this litigation qualifies as an "exceptional case" meriting a fee award under 35 U.S.C. § 285, because Takeda purportedly should have known that its infringement suit was meritless following *Zydus II*. ECF No. 106. Zydus requests fees and disbursements totaling $827,398.94. *See* ECF No. 106-1, Declaration of Marc Youngelson ¶ 3; ECF No. 106-3, Declaration of Steven J. Moore ¶ 6. Takeda opposes the motion on grounds that its infringement suit is not an "exceptional case." ECF No. 108.

[4] The Court ultimately dismissed Zydus's counterclaims for lack of subject-matter jurisdiction. *See* ECF No. 101.

Takeda also contends that Zydus's accounting of its fees is unreasonable, although Takeda requests an opportunity to respond to Zydus's accounting more thoroughly if the Court concludes that fees are warranted under 35 U.S.C. § 285. *See id.* at 13–14.

II. DISCUSSION

Courts may award attorneys' fees to a "prevailing party" in a patent litigation suit, but only in "exceptional cases." 35 U.S.C. § 285. Parties may demonstrate that a case is "exceptional" based on "the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014). The moving party bears the burden to demonstrate that a case is exceptional by a preponderance of the evidence, and "[d]istrict courts may determine whether" the party has satisfied its burden "in the case-by-case exercise of their discretion, considering the totality of the circumstances." *Id.* at 554, 557. Here, Zydus does not contest the manner in which Takeda litigated this suit, but rather challenges "the substantive strength" of Takeda's litigation position. *See* ECF No. 106 at 16–17.

In determining whether a case is exceptional based on the strength of a party's litigation position where claim construction is at issue, the court must assess the "substantive strength" of the party's position based on the relevant law and facts, *Octane Fitness*, 572 U.S. at 554, without conducting "a 'mini-trial' on the merits," *see SFA Sys., Inc. v. Newegg Inc.*, 793 F.3d 1344, 1348–49 (Fed. Cir. 2015); *see also Asghari-Kamrani v. United Servs. Auto. Assoc.*, Civ. No. 15-478, 2017 WL 4418424, at *13 (E.D. Va. July 27, 2017) ("[W]ith respect to claim construction, because the claims were never fully resolved by this Court, the Court declines to award attorneys' fees on the basis of unresolved claim construction issues."). "A party's position on issues of law ultimately need not be correct" to avoid qualifying as "exceptional." *Newegg*, 793 F.3d at 1348. Rather, the court must simply determine whether the party's "litigating position was . . . so merit-less as to 'stand out' from

the norm." *Id.*

For purposes of claim construction, "[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art [("POSA")] when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Entm't America LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1313). The Federal Circuit recognizes "two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner*, 669 F.3d at 1365.

Zydus argues that this case is exceptional because the Federal Circuit's claim construction decision in *Zydus II* purportedly precluded Takeda's infringement claim, *see, e.g.*, ECF No. 106 at 17–19; but *Zydus II* had no such effect. This Court reached the opposite conclusion in denying Defendants' motion to dismiss based on collateral estoppel. *See* ECF No. 50. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips*, 415 F.3d at 1312 (quoting *Innova*, 381 F.3d at 1115). *Zydus II* construed "the claim term 'fine granules having an average particle diameter of 400 µm or less.'" *See* 743 F.3d at 1363–64 (finding "no indication in the claim that 400 µm was intended to mean anything other than exactly 400 µm," as "the phrase '400 µm or less' is not qualified by the word 'about' or any other indicator of imprecision"). Unlike Claim 1 of the '994 Patent at issue in *Zydus II*, Claim 1 of the '546 Patent does not specify a particle size associated with "fine granules." *See id.* at 4–5. Thus, *Zydus II* did not answer the question at issue here: whether a claim that contains the term "fine granules"—but does not specify a particle size—necessarily incorporates the particle size discussed elsewhere in the patent. Although there is no precedent holding that the absence of preclusion places a litigation position within the "norm," here, Zydus relies heavily on the purportedly preclusive effect of *Zydus II*. As this Court has found, because *Zydus II* did not preclude

Takeda's infringement claim based on the '546 Patent, preclusion, by itself, cannot provide a basis for concluding that this case is "exceptional." *See Sprint Commc'ns Co. L.P. v. Cequel Commc'ns, LLC*, Civ. No. 18-1919, 2021 WL 1820562, at *4 (D. Del. May 6, 2021) (concluding case was not "exceptional" even where court previously dismissed claims based on collateral estoppel because the "[p]laintiff reasonably could have expected the claims to be construed differently," and "when . . . collateral estoppel was applied, [the] [p]laintiff took action to resolve the case efficiently").[5]

Preclusion notwithstanding, *Zydus II*'s reliance on the common specification underlying the '994 and '546 Patents in interpreting the term "fine granules" lends some support to Zydus's position that Claim 1 of the '546 Patent contains a particle-size limitation. As Zydus emphasizes, courts must read claims "'in view of the specification,'" *Phillips*, 415 F.3d at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995)), which "'is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). Two aspects of the specification were persuasive in *Zydus II*. First, the specification differentiates between "fine granules" and "larger 'conventional' granules, which it defines as '400 μm or more of average particle diameter.'" *Zydus II*, 743 F.3d at 1364. The court reasoned that adopting Takeda's proposed 10% margin of error would destroy the "clear dividing line" between "fine" and "conventional" granules. *Id.* Second, the specification "explain[s] that the maximum particle size is 'practically 425 μm or less,' where 'practically' means that 'the particles may include a small quantity (about 5 weight

[5] This Court also held that Takeda's infringement suit asserting the '994 Patent against Zydus's reformulated product, which Takeda filed after *Zydus II*, was not a "sham." *Zydus Antitrust Opinion*, 2021 WL 3144897, at *16. The standard for demonstrating that a suit was a "sham" for purposes of antitrust liability is higher than the standard applicable in determining whether a case is "exceptional" for purposes of attorneys' fees. *See Octane*, 572 U.S. at 555–57. Nevertheless, the fact that *Zydus II* did not preclude an infringement suit premised on the same claim that the Federal Circuit construed, which contained a particle-size limitation, further supports the conclusion that *Zydus II* does not preclude a suit premised on a different claim, which omits any particle-size limitation.

% or less) of particles whose particle diameter is out of above described range.'" *Id.* The court concluded that it would be "impossible for a tablet to comply with the specification's maximum particle diameter of practically 425 μm (meaning that only 5% of particles have diameters larger than 425 μm) if it had a median particle diameter of 440 μm (meaning that 50% of the particles are larger than 440 μm)," as would arise with a 10% margin of error. *Id.* Zydus contends that the Federal Circuit's analysis of the specification applies with equal force to the '994 and '546 Patents.

But the context in which *Zydus II* consulted these aspects of the specification is not necessarily applicable here. The claim at issue in *Zydus II* referred to "fine granules having an average particle diameter of 400 μm or less." *See* 743 F.3d at 1362. *Zydus II* relied on the discussion of particle size in the specification to determine whether the claim recited a hard ceiling of "precisely 400 μ m or less," such that "the district court erred in reading a [10%] margin of error into the disputed claim term." *See id.* at 1363–64. By contrast, Claim 1 of the '546 Patent does not specify a particle size, and the parties did not dispute in their *Markman* briefs whether the claim recites a particle size with a hard ceiling versus one with a margin of error. Moreover, *Zydus II* relied on these features of the specification insofar as they confirmed the "clear and unambiguous plain meaning" of the claim term, which specified "'an average particle diameter of 400 μm or less.'" *See id.* at 1363–64. Because the claim at issue here does not specify a particle size, the discussion of particle size in the specification referenced in *Zydus II* does not "confirm[]" the "clear and unambiguous plain meaning" of "fine granules" as used in Claim 1 of the '546 Patent. The "plain meaning" of "fine granules" used therein does not necessarily entail a particular particle size.[6]

[6] Zydus contends that construing "fine granules" without a particular particle size is "folly" because "even compositions the size of [a] truck, which clearly would cause roughness in the mouth, would be covered." ECF No. 106 at 30. The Court agrees that Takeda's failure to specify a particle size complicates any inquiry into whether the "fine granules" asserted in Claim 1 of the '546 Patent are small enough to avoid roughness in the mouth. Nevertheless, for the reasons discussed *supra*, it does not necessarily follow that Claim 1 of the '546 Patent requires "fine granules" that adhere precisely

Courts may "depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal." *See Hill-Rom Servs., Inc.*, 755 F.3d at 1371. "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning," and it "must 'clearly express an intent' to redefine the term." *Thorner*, 669 F.3d at 1365 (citations omitted). Zydus contends that the specification for both the '994 and '546 Patents contains a "definition" of "fine granules" by stating that "[t]he 'fine granules' have an average particle diameter of about 400 μm or less, preferably 350 μm or less. . . ." *See* ECF No. 106 at 35 (citing '994 patent col. 12 ll. 58–61; '546 Patent col. 12 ll. 58–61); ECF No. 80 at 21. And as Zydus notes, *see* ECF No. 76 at 20, terms in a specification that are "set off by quotation marks" often denote a "definition." *See Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007).

But Takeda plausibly argues that this reference to particle size in the specification concerns a specific embodiment of "fine granules," not necessarily a definition that is generally applicable across the patent. *See* ECF No. 82 at 11–13 (showing that the language Zydus cites as a definition of fine granules refers to certain "above-mentioned fine granules," which, according to Takeda, is a "specific embodiment"). As Takeda notes, the specification refers to "fine granules" 72 times, and it does so in connection with several desirable characteristics other than particle size. *See id.* at 6–8 (discussing role of fine granules in "stably retaining the active ingredient," masking a bitter taste, and reducing acid resistance). Because courts may "not read limitations from the embodiments in the specification into [a] claim[]," *Hill-Rom Servs., Inc.*, 755 F.3d at 1371, Takeda plausibly maintains that it did not "act as its own lexicographer" by referring to particle size in reference to certain

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to the particle-size specifications, *i.e.*, precisely 400 μm or less, *Zydus II* adopted in connection with Claim 1 of the '994 Patent.

embodiments. *Thorner*, 669 F.3d at 1365; *see also id.* at 1366 ("We do not read limitations from the specification into claims[.]"); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.") (quotations omitted). Although the Court is not necessarily concluding that Takeda's interpretation is "correct," no such standard applies in determining whether to award attorneys' fees. *Newegg*, 793 F.3d at 1348.

Neither is "disavowal" readily apparent. "Disavowal requires that 'the specification [or prosecution history] make[ ] clear that the invention does not include a particular feature,'" *Hill-Rom Servs., Inc.*, 755 F.3d at 1372 (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001)), "or is clearly limited to a particular form of the invention," *Hill-Rom Servs., Inc.*, 755 F.3d at 1372 (quoting *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1330 (Fed. Cir. 2009)). Doing so typically requires "expressions of manifest exclusion or restriction." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). "[S]tatements such as 'the present invention requires[,]' or 'the present invention is[,]' or 'all embodiments of the present invention are[,]'" are examples of language that expresses disavowal. *Hill-Rom Servs., Inc.*, 755 F.3d at 1372 (citations omitted). In this regard, Zydus notes that the '546 Patent appears to contrast "fine granules" with "[c]onventional granules" that have "a large particle diameter (400 μm or more of average particle diameter)" and "produce a feeling of roughness in the mouth." *See* ECF No. 76 at 21 (citing '546 Patent col. 2 ll. 22–28). But as Takeda responds, the reference to "[c]onventional granules" appears in the Background Art section, not the specification, *see* ECF No. 82 at 14, and in any event, "[m]ere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal." *Thorner*, 669 F.3d at 1366. Zydus's *Markman* expert also acknowledged during a deposition that a POSA

would not necessarily understand there to be a hard 400 μm cutoff between granules that produce roughness and those that do not. *See* ECF No. 82 at 15 n.4 (citing ECF No. 82-4, Deposition of Michael Crowley, Ph.D. Tr. 125:15–20). Takeda therefore presents at least a plausible argument that the specification does not disavow "fine granules" recited in Claim 1 of the '546 Patent that are above 400 μm in diameter.

Moreover, although both parties identify evidence from the prosecution history supporting their proposed constructions, that evidence is largely in equipoise; the scales do not so tip in favor of Zydus such that I can find that Takeda's position is abnormally weak. Takeda emphasizes that whereas Claim 1 of the three earlier patents in the same family specify a particle size, Claim 1 of the '546 Patent does not, demonstrating Takeda's intent not to include such a limitation in the '546 Patent. *See* ECF No. 75 at 12; ECF No. 82 at 8–10; *see also Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1356–58 (Fed. Cir. 2004) (holding that progression in scope of claim asserted in child patent compared to parent showed that the patentee "purposefully sought" a broader scope in the child, to which the "patentee is entitled" absent other evidence of lexicography or disavowal). By contrast, Zydus identifies a July 2016 response Takeda sent to a Patent Examiner in connection with the '546 Patent, which, according to Zydus, constitutes an admission "that 'the present invention . . . comprises fine granules.'" *See* ECF No. 76 at 23–24. The relevant passage states:

> The present specification discloses that the invention of the present claims are related to a tablet, granule, fine granule, capsule, effervescent, or suspension preparation, which comprises fine granules (see item [49] at page 9, lines 4-6, and see also item [32] at page 7, lines 29-33 of the specification (emphasis added)). The specification clearly distinguishes "an effervescent" preparation from other alternatives, such as a tablet, granule, fine granule, capsule, and suspension preparations. . . .

See ECF No. 82 at 17; ECF No. 76-19 at 4 (underlining in original). This passage does not mention particle size, but "item [32]" of the specification referenced therein provides: "fine granules having an average particle diameter of 400 μm or less . . . ." *See* ECF No. 76-3 at 5, '546 Patent col. 4 ll. 50–

51. Takeda nevertheless insists that the July 2016 response was unrelated to particle size and was intended to identify "an effervescent as an alternative preparation for the orally disintegrable tablet to support the exclusion of an effervescent from the claimed [ODT]." *See* ECF No. 82 at 17–18; Polli Decl. ¶ 64. This position is plausible given that the stated purpose of Takeda's response is to support a claim that the ODT is not an effervescent, *see* ECF No. 76-19 at 3, and Takeda emphasized the word effervescent by underlining it. As such, both parties' positions have some merit, and it is not evident that Takeda's position is weak enough to "stand out" from the "norm." *Newegg*, 793 F.3d at 1348.

Based on the foregoing discussion, the Court is unable to conclude that the "substantive strength" of Takeda's infringement claim "stands out from others" such that this qualifies as an "exceptional" case under 35 U.S.C. § 285. *Octane Fitness*, 572 U.S. at 554.

III. CONCLUSION

For the reasons set forth above, Zydus's motion for attorneys' fees is **DENIED**. An appropriate form of Order is filed herewith.

Date: May 18, 2022

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
U.S. Chief District Judge